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Published in:
Procedia CIRP

Link to article, DOI:
10.1016/j.procir.2018.04.066

Publication date:
2018

Document Version
Publisher's PDF, also known as Version of record

Available online at www.sciencedirect.com

ScienceDirect

Procedia CIRP 75 (2018) 261–266

www.elsevier.com/locate/procedia

15th CIRP Conference on Computer Aided Tolerancing – CIRP CAT 2018

The Applicability of CAT tools in industry – boundaries and challenges in tolerance engineering practice observed in a medical device company

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Abstract

While the capabilities of computer-aided tolerancing (CAT) tools are increasing continuously, their compatibility with design processes in industry is not necessarily a given. This paper seeks to examine potential method barriers and challenges that limit the applicability and general uptake of CAT software in industry, through interviews with practitioners ranging from tolerance engineering specialists to project managers. The study identifies several issues met by practitioners that limits or prevents their use of CAT software, pointing to several unmet needs.

Peer-review under responsibility of the Scientific Committee of the 15th CIRP Conference on Computer Aided Tolerancing - CIRP CAT 2018.

Keywords: Tolerance design, Tolerance analysis and variation simulation, Computer-Aided Tolerancing

1. Introduction

The rapid advances in the capability of computer-aided design software have enabled mechanical designers to develop increasingly advanced products, with a high degree of functional integration and mechanical complexity. While these ongoing advances have had positive impact on technology development, they do increase the work required to ensuring the manufacturability and robustness of products. A key step here is tolerance design, which engineers have a tendency to overlook in many industries, seeing as "*it all fits together in CAD"*. The tolerance design process may in many cases seem simple; defining the acceptable range of variation on the size, shape, orientation and position of a feature. In reality, however, the amount of calculations and iterations involved in designing high volume products, can become time consuming. As a result, CAD providers are increasingly developing solutions for computer-aided tolerancing (CAT), in order to support designers in dimensioning tolerances and analyzing the influence of variation. Through a case study within the medical device division of a major pharmaceutical company, this paper aims to illustrate some of the challenges met by engineers working with tolerance design and analysis, to gain an understanding of why CAT tools are sometimes disregarded in organizations that develop physical products.

2. Aim and scope

The case company has on several occasions considered the implementation CAT software, having used most of the leading software solutions on a trial basis, but has stuck with a more manual approach. Focusing on developing medical devices for high production volumes, the company has an extensive focus on variation risk management, and has controlled procedures in place, to fully quantify the influence of variation upon their products. This is primarily driven by the safety and cost intensive nature of the medical devices.

This paper aims to illustrate some of the boundaries to the uptake of CAT software, by investigating the challenges met by practitioners throughout the tolerance design and analysis (TD&A) process. As such, this work seeks to answer the following questions, in the context of the case company:

- What methodologies and processes are involved in tolerance design in the organization?
- What issues arise and where do they stem from?
- What needs must CAT software fulfill, to provide value throughout the product development process?

The primary focus here is to gain an understanding of the inherent challenges related to tolerancing in practice. As such, testing and comparing the actual capabilities of existing

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Peer-review under responsibility of the Scientific Committee of the 15th CIRP Conference on Computer Aided Tolerancing - CIRP CAT 2018.
10.1016/j.procir.2018.04.066

software solutions in detail, is beyond the scope of this work. While observations from a single case company may not necessarily fully describe the boundaries and challenges related to TD&A in industry, they still serve to show that challenges exist, even in variation risk averse organizations.

3. Methodology and approach

To find answers to the defined research questions, data was gathered through a case study, and a literature study which was used to contextualize the findings of the case study. Following the methods defined by Ahmed, S.[1] for empirical research in engineering design, the case study consisted of interviews with a variety of engineers on different levels of specialization and responsibility in the case company.
The case company develops new products in project teams consisting of a group of project engineers led by a lead engineer. The teams are supported by a division of specialists within variation risk management (VRM). For the purposes of this research, four specialists, two project engineers, two lead engineers and a manager responsible for VRM within the company, were interviewed. The specialists were interviewed to gain insight into internal methodology, the division and size of the appertaining task, and use of software tools. The lead engineers and project engineers were interviewed to get a real world view on the existing processes, methods and tools associated with TD&A, while the manager was interviewed to gain insight into the prioritisation and planning of VRM tasks. The quotes in this article are in some cases paraphrases, seeing as they were given in different languages and contexts.

Furthermore, the companies' own tolerance design training program for new engineers was attended to gain an understanding of the internal procedures and approaches related to work with TD&A. All engineers within mechanical product development tasks are required to complete an internal tolerance analysis training program. This training program aims to give non-specialists sufficient competencies to perform tolerance stack-up analysis. The training program also aims to align the way engineers work with TD&A, with existing processes and procedures within the company.

Literature within the field was studied to contextualize the observations made in the case company, in order to relate them conclusions drawn in other works, and to examine whether the observations are contextually independent, or inherent to the case company. While the volume of literature on TD&A is extensive and continuously developing, existing research within the field has little focus on the actual needs of industry with respect to the successful application of computer-aided methods in TD&A. The exceptions to this rule are case studies showing the successful cases CAT implementation, which does not necessarily help clarify whether CAT software generally meets all the needs of practitioners in general. The research focus rather seems to be on the development of mathematical/statistical methodology, software development, improved CAD integration, tolerance optimization, tolerance strategies and their appertaining management processes. Studies within Variation Risk Management [2]. computer-aided tolerancing [3, 4], closed-loop tolerance engineering, and of the limitations of tolerance analysis methods [5,6] were reviewed and used . The literature found, was as such used to contextualize the findings of the empirical study and as a basis for identifying which needs are unmet by existing software solutions.

4. The tolerance engineering process observed

For the sake of clarity, the findings of the case study have been divided into two sections. First, the observations on the tolerance engineering process in the case company are presented. Subsequently, the observed internal difficulties surrounding tolerance design, with respect to both methods and to computer aided tools are discussed. These results are continuously related to the existing literature within the field.

The TD&A process at the case company characterized by the safety intensive nature of medical devices. The worst-case consequences of unmitigated, improper tolerance design are threefold; increased scrap rates in production, increased risk of failure, and loss of quality. The TD&A process is therefore set up strictly to ensure that products meet requirements. All tolerance stack-ups are required to fall within product specifications, or production requirements – ideally through design, or through tightened tolerances (rare cases). Products are simply not manufactured unless this requirement is met. Continuous design reviews, and resulting design iterations, ensure that these predefined product and production requirements are met. As development is continued until tolerance analyses show that the design falls within spec, issues with TD&A can have a drastic influence on the lead time of a product. The case company therefore has an interest in streamlining the TD&A process as much as possible:

"Developing devices is becoming more and more complex; with more functions come more tolerance loops.…. it just takes longer than it used to. If there were a quicker way to do tolerance analysis, I would be all for it"

-Lead Engineer

Overall, the TD&A process at the company is built around identifying features of interest and their corresponding requirements. Features of interest are an internal term for pinpointing the geometric features which are linked to some type of function or quality requirement – i.e. an overlap, clearance, a contact surface, alignment or similar. By defining requirements for these features – the acceptable range of variation in geometric functionality – engineers are then able to evaluate the effect of variation. This process directly resembles models on handling variation, based on findings from industrial research. The VRM framework [2], presents an iterative three step process to dealing with variation, namely risk identification (key characteristic identification), risk assessment, and risk mitigation One might argue that the entire TD&A process at the company follows this line of thinking. By identifying features of interest and their requirements, engineers are actually identifying the geometric features that influence function or quality, that are at risk of being affected by variation. In other words, features of interest and their requirements are analogous to key characteristics in the VRM framework. Ensuing analysis activities are by definition therefore strategies for risk assessment.

When products are re-designed or tolerances are tightened based on the tolerance analysis, the variation risk is mitigated. The entire TD&A process at the company can therefore be described using the terminology defined in the VRM framework. The engineers also use predefined guidelines on the fineness of tolerances, usually aiming for designs comply with predefined tolerance grades on the IT-scale [7], with tightened tolerances being a last resort which is only applied if re-designs are not possible. Although finer tolerance grades are achievable, the range of acceptable tolerance has been defined based on cost efficiency and on process capability. One can therefore not claim that the TD&A process at the company follows the *Closed Loop Tolerance Engineering* process put forward by Krogstie et al [8]. The reasoning behind this is that feedback loops between tolerancing and process capability (PC) are more or less non-existent, unless tolerances are reduced in the rare cases where re-design is not possible. Based on tolerance training material at the company, the risk assessment stage consists of three sub-stages:

Tolerance Representation

This involves the creation of an overview of the tolerance loops starting with identifying the parts and interfaces involved, and the direction of the tolerance loop. This also involves some form of visualization to support the process.

Tolerance Specification

This involves annotating the geometries included in the loop and specifying tolerance ranges on parts and assemblies, and defining checksums for later result verification.

Tolerance Analysis

This involves setting up the governing equation for the tolerance loop, and performing the actual analysis. Time is also spent on visualizing and documenting the results.

This sequence is repeated for each key characteristic built into the product. The chain of events is comparable to the types of overall functionality built into most commercial CAT software, as discussed in by Prisco and Giorleo [4]. With respect to the overall tasks at hand, one would then assume that existing software could support the TD&A process – the question is just, whether it would be of use in alleviating some of the issues that occur throughout the process.

Seeing as engineers at the company perform tolerance analyses by compiling the variation of each individual part, into total variation, one could characterize the assessment of risk as being bottom-up, following the approach of Rivest et al. [9]. Tolerance chains, defined based on the individual process variations, are in other words a strategy for assessing the final product quality. If product quality does not match the product specification, then redesigns are performed.

4.1. Division and size of task

In the development of new products, the tolerance engineering tasks are distributed amongst engineers at different levels, to ensure the effective use of competencies. A tolerance specialist is for instance not necessarily required to be involved full time throughout an entire development project and the working hours of the specialists are therefore distributed across the different development projects. The specialists are only required to assist with the basic calculations, and are called upon for more advanced analyses. In practice however, the level of complexity seen in the early "*basic*" calculations often results in specialist engineers being called on to perform more or less the entire task, especially when development projects are under time constraints:

> *"Sometimes we end up doing most or even all of the tolerance work in projects. Either they simply don't have the time, they don't have enough engineers with tolerance engineering competencies, or the task is simply too complex."*
>
> -Tolerance Specialist

Beyond the 4 full time tolerance specialists, and 5-6 drafting technicians who aid the documentation process, the size of the TD&A task at is difficult to assess, seeing as the time spent varies drastically depending on the project:

> *"It's difficult to say - development projects spend some-.where between 9-24 man-weeks on tolerancing a year beyond specialist help. With up to 10 projects running in parallel, a lot of lead time goes to tolerance design and analysis"*
>
> -Manager

4.2. Tools

The tools and methodology surrounding TD&A in the company depend on the level of analysis, and the maturity of the product being developed. The tools and methods used are listed based on how early in the design process they are used:

- A handbook containing, amongst others, a tolerance design guideline and rules of thumb for the process capability in the company.
- 2d sketches of the tolerance chain being analysed
- A proprietary CAD system – all parameters requiring tolerances are annotated in the nominal CAD model.
- Microsoft Excel Template developed by the tolerance analysis specialists. Using imported CSV files, CAD data is input as data for a tolerance stack-up analysis.
- A VBA based interface between the CAD system and Excel - this interface is one-way.

The core tools in the TD&A process are therefore 2d drawings, the CAD system, and the tolerance analysis calculation sheet. The calculation sheet is a highly integrated tool, with both tolerance stack-up and fit analyses capabilities, with planning tools and a post-processing module built in as well. The company does not use proprietary CAT software, although CETOL and 3DCS have been used on a trial basis:

> *"…we decided against the use of CAT software – it simply didn't speed the process up compared to our own tools. They also often rely on a level of CAD fidelity we simply do not spend time on reaching during the early stages"*
>
> -Tolerance Specialist

5. The tolerance engineering challenges observed

CAT software can only truly be of value to if it changes the current work-flow to the better, reducing analysis work, and aiding engineers in their design process. In other words, the CAT software needs to outperform the existing use of CAD output into a Microsoft Excel template to perform analyses.

In order to assess the applicability of said software, the engineers were asked to describe their grievances with TD&A and to give examples of situations in which TD&A led to problems. These interviews revealed several areas in which issues with TD&A occur. As shall be discussed, most of these issues stem from the complexity of the TD&A task at hand, and the design uncertainty that affects the development process. Overall, the core issues fall within four categories:

5.1. Tolerance design workflow

The work-flow surrounding the TD&A process is somewhat removed from the ideal tolerance engineering process described in literature. This is primarily driven by the unavoidable iterative nature of the development process within the company, where the product requirements and overall product concept changes over time. Tolerance engineering tasks are by no means popular, with engineers at all levels expressing a degree of frustration over the complexity of the analysis, and the ease with which one "gets lost" in the analysis. Commonly, the full tolerance analysis is seen as a part of the "final stretch" before the design freeze, instead of being a consideration throughout the process:

"Doing a full tolerance analysis is not worth it until the end – the design is going to change drastically anyway."
- Project engineer

…it's so easy to get lost, when you have dozens of loops and hundreds of parameters, which change throughout."
- Tolerance engineering specialist

In general, the company is very proactive in managing variation, with robust design practices being involved from beginning to end. With respect to tolerance design activities however, engineers are often fully aware of the key characteristics of the system, they do not assess the actual risk until late stages of development. At times the task is delayed until the process of transfer to production begins:

"They're the least popular assignments – and they're always done at the last minute. Often because the design changes so rapidly, that it does not provide value until the end
- Manager

It would be nice if there was a tool that included standardized analyses. We're looking at the same types on interfaces all the time anyway. We keep re-doing the work
-Lead engineer

Not only are TD&A activities occurring late in the design process – they are also lack appeal. This apparent lack of popularity of TD&A indicates that engineers might be meeting some methodological barriers. With the integrated nature of medical devices the risk is that otherwise simple tasks become complex. It may be worth considering whether there is a need for methods that allow some form standardized analysis, as is seen in some areas of structural mechanics?

5.2. Tolerance chain identification

A key prerequisite in performing tolerance analysis is to be able to pinpoint what parts influence a tolerance chain, and what their contribution to the overall stack-up is. A difficulty in maintaining an overview of internal relations between each component and the properties of the assembly in products seems to be a core limitation in performing accurate analyses.

A limitation to performing fast and accurate analyses seems to be the inherent difficulty in maintaining an overview over the relations between the components in an assembly:

"You have to know the product so well, to correctly identify the chain and features that make up each chain….my experience is that project engineers are very adept in identifying the feature of interest, but get lost in identifying the interfaces involved, and defining their contribution"
-Tolerance Specialist

Unfortunately, automatic or assisted tolerance chain identification is not – based on the findings of the literature study - a capability embedded into CAT software. Existing software requires the user to select the parameters involved in the analysis. If the engineer is having trouble identifying the parameters that influence the variation of a KC, CAT will be of little help compared the existing procedure. There is some research on methods for automatizing the chain identification process, such as Wang et al [10], but any applicable solution to the issue has not been found commercial software.

5.3. Visualization of variation

Somewhat related to the issues with identifying the geometric constituents of tolerance chains, is the lack of a tool to visualize the effects of variation (e.g. CAD):

"It's so difficult to imagine out what the variation modes are in each subsystem and interface. Is it shift, alignment, rotary deviation, or something entirely different?"
-Project Engineer

As this quotes point towards, visualization is an important part of tolerance chain identification. How can one identify the what features influence a stack-up without either being able to imagine it, or through visualization? There is no practical way of getting CAD software to show the geometric consequences of variation. If an engineer wants to check how the applied tolerances affect the model, he/she would have to do it manually, changing parameter values in CAD. As a result, hand-drawn sketches are a simple way to visualize the effects of variation in the early stages of tolerance analysis.

5.4. Interaction between CAD model and analysis

As discussed in the Tools section, the connection between CAD- model and Tolerance Analysis is one way:

"The analysis was "green" for several months. During the design review, we discovered a feature in the model that had been changed, but not in the analysis."
-Lead Engineer

With development projects at the company often lasting several years, the amount of re-designs conducted throughout the product development process is substantial. With features being redefined continuously design uncertainty affects the applicability of existing tolerance design methods in early design stages. The connection between CAD and analysis currently allows engineers to update the analysis when changes are made in the CAD model, but only if existing parameters are altered. If new parameters are created through redesign, then the tolerance analysis previously performed needs to be reworked, either partially or entirely, depending on the size of the change. The process is also manual – for every model change, the export/import procedure is required.

6. Observed needs

Based on the findings from the empirical study and from literature, one can define a set of requirements for the ideal CAT software, with respect to application at the case company. These requirements are based on the key issues that occur in tolerance design, upon the activities central to performing accurate tolerance analysis, and upon ensuring ease of use. These requirements are divided into two categories, depending on their level of importance. *Primary requirements* are capabilities, and properties that CAT software needs to possess, if it is to be applicable at the case company (i.e. "*need to have*"). They are based upon the key limitations of the existing process, as identified in the empirical study. If these requirements are not met - either partially or completely - then there is little benefit in using CAT over the existing tools. *Secondary requirements* are capabilities and properties that could add value, but which are not essential in performing TD&A (i.e. "*nice to have*").

6.1. Primary requirements

To fulfill the needs expressed by the practitioners in the study, replacing manual tools, CAT software would have to:

- Be directly- or partially compatibility with the CAD/CAM platform used within the company
- Allow a form of live-link between model and analysis
- Give verifiable and transparent results
- Allows swift specification and chain identification
- Supports Part and assembly level analysis
- Supports rotary, positional and orientation analysis

As the empirical study has pointed towards, design uncertainty necessitates some form of link between CAD model and tolerances analysis. Without it, performing tolerance analysis in the early stages of development, becomes time consuming, when one accounts for the added work redoing and updating the analysis as the design changes.

This link can be achieved in two ways – either the CAT software is directly integratable with the CAD system used at the company, or it accepts fully versioned files from it. If CAT software is able to process files generated directly from CAD, updating the tolerance analysis would merely entail synchronizing files between directories (CAD->CAT) – assuming that the analysis itself remains unaffected.

With the continual design changes throughout the development process, and the wide range of kinematic states that the product can assume, designers need to be able to annotate and define analyses swiftly, without too much parametric work. As discussed by Schleich et al [3] commercial CAT software is incapable of automatized tolerance chain identification and including form variation in analysis. This conclusion, along with this research, proves that little has changed since Prisco & Giorleo reviewed the capabilities of commercial CAT software in 2002 [4]. Wang et al [10], and Söderberg et al [11] did however propose a methodology for automated tolerance chain identification.

Some CAT solutions are oriented towards only performing analysis of assembly- or part level variation [4], and do not necessarily support modeling of all sorts of variation, which provides little value when analysing integrated products on a system level. Furthermore, without transparency of results from CAT software, engineers have no chance of evaluating the accuracy of their work.

6.2. Secondary requirements

- Capable of visualizing the different variational modes of a system
- Compliant with GPS
- Automatic tolerance reporting
- Able to input analysis archetypes; press-fits, clearance, alignment etc.
- Sensitivity analysis and optimization capability
- Advanced statistical modelling

The ability to visualize the geometric effects of variation is a central to the TD&A process, as engineers have expressed a difficulty in actually imagining the influence and effect of different forms of variation. While integrating sensitivity-, kinematic analysis along with tolerance optimization, could be useful for design engineers, these activities provide little value, if assistance in actually finding the contributors to a tolerance chain is not effective. What good is optimizing a tolerance chain, if all the parameters involved are not included? Why is this attractive, when engineers who work with tolerance design still lack tools for efficient tolerance chain identification, automatized analysis updating from CAD, and visualization of variation?

7. Discussion

As identified in the empirical study, tolerance engineering considerations are at times not included until the final stages of a product development phase - just before design transfer. This points towards an overall difficulty in the actual design process. As discussed by Thornton et al [2], the sooner variation risk management strategies are included in the design process, the cheaper and easier it becomes to ensure both a sufficient product quality, and manufacturing efficiency. Viewed in the context of the VRM maturity framework, continuing on the work of Rivest et al [9], it can be argued that the case company semi-proactive when it comes to tolerance design and analysis. Stack-ups and tolerance modeling is mostly conducted during the late stages of development , seeing as "*things are re-done anyway*".

According to Thorton et al., the lack of maturity can either be attributed to management not supporting VRM practices and/or designer's inability to identify and KCs and the effects and risk of variation. As discussed earlier, VRM practices are core to the business of the company, and it can therefore not be a question of a lack of support for VRM practices.

Eifler, Ebro and Howard [12], meanwhile, argue that the lack of operational tools can be a key factor in late or lacking application of robust design methods. In complex systems, tolerance analysis can be very inefficient in early stages, seeing as the design is going to change. Furthermore engineers have clearly expressed frustration with the lack of appeal and complexity of tolerance analysis methods. Given the focus upon- and amount of training within TD&A in the company, the inability of designers at should in other words not in any way be attributed to the competence of the designers, but rather to a methodological barrier. This barrier stems from two factors – a high degree of design uncertainty, and a high degree of complexity in the required analysis. That being said, it remains to be seen whether the challenges observed are unique to the case company.

Given that tolerance design and analysis is a key VRM strategy for high volume products, there is a potential in striving to apply tolerance engineering at an earlier stage of development. This would, however require the development of new methods, given the high degree of design uncertainty. How is a designer otherwise to know the consequences of a design decision upon tolerances, when the design and its requirements are going to change a multitude of times?

Using computer aided tolerance analysis software is by no means a miracle solution to the difficulty in foreseeing the effect of tolerance stack-ups on the performance and quality of products. So far, no practical way of including form tolerances in computer-aided analyses exists (although this is difficult in manual analyses as well), and all CAT software have mathematical assumptions embedded, which might not always be applicable. Furthermore, only the RD&T software package allows geometry based analysis, with all other commercial software seemingly performing point based analyses [3]. All CAT software is, in other words, giving results based on "points in space" and not actual geometries.

No existing software solution is able to handle both faultless, rigid body analysis for early stages and late stage advanced analyses that include second order effects. As discussed by Stockinger et al [13], the only way to capture the full effects of variation from manufacturing and assembly processes, is to perform full-on finite element analyses simulating all the involved processes, all the while taking variation into account. This procedure is generally too time consuming and computationally expensive to perform in most development projects. Moreover, the quality of results obtained in CAT, is dependent on the designer selecting the correct measurement references and defining kinematic relations correctly, be it through the CAD model or manually. If the designer overlooks a key characteristic, and excludes it from analysis, CAT software will not be of any help. Actually identifying the KC requiring analysis is still in the hands of the designer, and failure in this crucial task will lead to incorrect interpretations, giving a false sense of security. CAT software can in other words, not replace a sound sense of variation risk, just as finite-element software cannot replace a sound understanding of solid mechanics.

8. Conclusion

The research conducted has resulted in empirical observations which are consistent with several frameworks on management of variation and tolerance engineering. In doing this, several challenges in tolerance design and analysis, have been uncovered, which have not previously discussed in existing research. Examples include the lack of a link between CAD and tolerance analysis, and that a lot of the tolerance analysis work can be somewhat generic, even in complex products. The challenges involved in actually identifying tolerance loops, may be one of the key barriers preventing more widespread uptake of CAT. Finally, the requirements to CAT software that have been derived from observations from engineering practice, indicate that there could be a discrepancy between the what CAT software providers focus on as their key offerings, and what capabilities practitioners actually need, at least in the context of the case company. Further work would therefore be to investigate whether similar challenges are seen in other companies and industries, and if so, whether the unmet needs are the same.

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